UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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PRE-PROPOSAL CONFERENCE

RFP-HHS-BARDA-08-09:

BUILDING PANDEMIC CELL-BASED INFLUENZA VACCINE MANUFACTURING FACILITIES

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FRIDAY, SEPTEMBER 12, 2008

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The pre-proposal conference convened at 9:00 a.m. in Room 325A of the Hubert Humphrey Building, 200 Independence Ave, SW, Washington, DC.

PRESENT FROM HHS:

MICHAEL ANGELASTRO
CHARLES CURRAN
SCHUYLER ELDRIDGE
CHRISTINA HARTMAN
ROBERT HUEBNER
VIJAYA MURTHY
PAQUETTA MYRICK-HANCOCK

MICHAEL PERDUE

THOMAS WARF

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Dr. Mike Perdue	

1	P-R-O-C-E-E-D-I-N-G-S
2	(9:06 a.m.)
3	MR. WARF: Okay. I would like to
4	welcome everybody, and start off the
5	conference now, and introduce Dr. Michael
6	Perdue. He is the Acting Director of the
7	Pandemic Influenza program, which is now
8	changed to IEDD, which is not an explosive
9	device, talks about influenza and emerging
10	diseases. Dr. Perdue.
11	DR. PERDUE: Thanks. Yes, on
12	behalf of our division in BARDA, let me
13	welcome you to today's proceedings. And as
14	you all know, the Secretary has great interest
15	in development of cell culture produced
16	vaccines on our soil for rapid response to
17	potential pandemic, and also other emerging
18	diseases. And our group is a program
19	responsible sort of for delivering advanced
20	development and acquisition of the
21	countermeasures for pandemic flu, so I think
22	you're all aware of our role within BARDA, and

1 BARDA's role within the U.S. government.

2. Today, we have the opportunity to 3 answer questions for you, and we have our top 4 people, I assure you, from our division, as 5 well as the Contracting Office on this because it is a fairly high profile endeavor and 6 7 contract, so we look forward to interacting with you. If there's anything the program can 8 9 do, our division can do for you, please let me 10 know. Otherwise, I'll turn it over to these 11 guys to answer the questions. Turn it over to 12 Mike.

MR. ANGELASTRO: Okay. Thank you,
Dr. Perdue. First off, I'd like to just go
around on the government side of the house
here and do a quick introduction, make sure
everybody knows who the players are. My name
is Mike Angelastro. I'm the Contracting
Officer's Technical Representative, formerly
known as Project Officer for this
solicitation.

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MR. WARF: I'm Tom Warf, and I

- 1 serve as the Program Manager for the overall
- 2 facilities program.
- 3 MR. CURRAN: My name is Charlie
- 4 Curran, and I'm here with the Office of
- 5 General Counsel, the General Law Division,
- 6 sort of give some guidance on the legal side.
- 7 MS. MYRICK-HANCOCK: Good morning.
- 8 My name is Paquetta Hancock. I'll be the
- 9 Contracting Officer for this requirement.
- 10 DR. HUEBNER: I'm Bob Huebner.
- 11 I'm a Senior Program Manager working in cell
- 12 based vaccines and stockpile.
- 13 MR. ELDRIDGE: Schuyler Eldridge,
- 14 Contracting Officer.
- 15 MS. MURTHY: Vijaya Murthy,
- 16 Contract Specialist.
- 17 MS. HARTMAN: Christina Hartman,
- 18 HHS.
- 19 MR. ANGELASTRO: Good. Thank you.
- I'm now going to turn it over to Paquetta, who
- 21 will give you some brief overview of today's
- 22 proceedings, how we're going to structure the

1 meeting.

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MS. MYRICK-HANCOCK: Okay. I'd

just like to mention two things. First of

all, I'd like to make sure that everyone

signed in that's actually here in attendance.

If there is anyone who hasn't signed in,

please do so.

What we're going to do is we prepared some responses to the questions that were submitted by the deadline that we'd like to go through. Mike is going to take you through a slide presentation with those responses.

We're also going to give -- then 14 15 we're going to have a break, 15-20 minutes. We're going to allow you during the 16 17 presentation to note your additional follow-up questions that you may have on these index 18 19 During the break, we'll collect these, cards. 20 review it, and see if we can provide you with 21 the additional responses for them. And if anyone needs more, please let me know. 22

1 MR. ANGELASTRO: Also, as you may 2. or may not have noticed, the room is wired. 3 We're recording the proceedings today, so that 4 a transcript can be created for posting on 5 FedBizOpps. All right. 6 MS. MYRICK-HANCOCK: There's also 7 a copy of the handout. 8 MR. ANGELASTRO: What Paquetta is 9 distributing right now is a handout of the 10 formal responses to the questions that were 11 pre-submitted for this RFP. I have them on 12 the slide deck here. We'll go through them in 13 detail, but if you wanted to see the full question, because some of the questions 14 15 actually had some -- a preamble to them, and I wanted to make sure you have the full text. 16 17 So, let's get started.

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Question number one is, "Are costs associated with deliverables that are not part of earlier awarded contracts to be included in the overall proposal costs?" And our response to that is, "Costs that support the technical

1 elements of this RFP, but are currently funded with other U.S. government contracts should be 2 3 identified as such in the business proposal. Those costs should not be included in the 5 final estimate." Of course, that all goes into the business proposal element of the 7 contract, so we want to avoid double billing situations, as well as confusion with other 8 9 existing government contracts.

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Question number two, "What should be the basis for projected pandemic vaccine strain yields", a manufacturing or production side of the house question. So, "The U.S. government will accept an average yield based on the performance of influenza strains manufactured as part of contracts administered under other BARDA contracts." And, "Yes, the offerors may assume that facility design and capacity calculations can be based on yield data of seasonal influenza strains on the offeror's cell substrate."

Question number three, "Can Health

and Human Services clarify its position on 1 2. indemnification if the pandemic vaccine requested to be made by Health and Human 3 4 Services under this RFP is not an already 5 licensed vaccine?" This is a legal question, and, "The government has taken the comments 7 under consideration, weighing a number of options about how to best address contractor 8 9 concerns in this area, and a more definitive 10 response to the question will be provided as 11 part of any amended RFP." So we're working 12 through that with our General Counsel. 13 Question number four, along similar lines, legal question, "Can Health and 14 15 Human Services clarify the status of the U.S. government's position on the issue", and the 16 issue being intellectual property, "and 17 whether or not a formal waiver for this 18 19 potentially restricted criteria would be 20 afforded by Health and Human Services."

revolving around re-assorted reverse genetics

the issue at hand is intellectual property

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1 technology. And, "Does HHS have an agreement 2. in place that allows other parties to use the technology in conjunction with Health and 3 Human Service's affiliated warm based 5 manufacturing contracts, or in the event of a pandemic?" And similar response to question 7 number three, taking that comment under consideration, and we're looking at a formal 8 9 response for that.

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Question number five, "Does HHS anticipate amending the referenced September 29th proposal submission date of the RFP to a later date to allow offerors to compile a proposal that better meets the requirements of DHHS?" And the answer to that is no, proposal submission is due 3 p.m. on September 29th, so we're not extending the proposal due date.

And the next slide outlines our aggressive schedule, as Dr. Perdue has highlighted. We have a time line to award that's rather aggressive, but it's also a high priority of the Secretary of Health and Human Services, so

1 we're shooting for a target of December 15th 2. for contract award. And as we backdated our 3 work, we realized that the last possible date 4 that we can accept the initial round of 5 proposals would be September 29th. So this is an outline of what the process is, starting 7 with September 29th. October 28th is when 8 we'll determine our competitive range. 9 November 28th, the final proposals will be 10 due, after a period of Q&A between the 11 Contracting Officer and the offerors. December 5th will be award recommendations to 12 13 our HHS Leadership, and hopefully by December 15th, we'll have contract award, and there'll 14 15 be a merry Christmas for everyone. Everybody 16 got notes on that. Question number six, "To 17 Okay. what extent does Health and Human Services 18 19 anticipate having materials stockpiled to 20 enable fill and finish of vaccine, if such a 21 shortage of non-offeror materials should 22 occur?" So we're talking about vials, and

syringes and things of that sort. And the 1 2. materials for finishing doses will be the subject of another RFP issued by BARDA. 3 So as 4 you can tell in this RFP, if we do have a 5 declared pandemic or when we have a declared pandemic, the manufacturer of the 150 million 7 doses will be a separate solicitation. then these elements will be captured in that 8 9 solicitation.

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Question seven, "Assuming that an offeror does not currently have funding from Health and Human Services for all required clinical trials for licensure of a pandemic vaccine, will the clinical bridging studies to be funded by Health and Human Services through this mechanism include conducting clinical trials required by FDA for licensure of a pandemic vaccine?" And the answer to that is, "The clinical bridging studies will be funded; however, studies that are required by CBER to achieve licensure will not be funded."

Question eight - the next few are

1 a little long. Question eight, "Is HHS 2. willing to modify or remove the mandatory requirement for successful completion of Phase 3 4 I clinical trials for a mammalian cell-based 5 influenza vaccine candidate as a prerequisite 6 to the proposal submission?" 7 To answer that question, 8 specifically, "No, the mandatory requirement 9 for successful completion of Phase I clinical 10 trials for a mammalian cell-based influenza 11 vaccine candidate as a prerequisite to 12 proposal submission will not be removed." 13 The second question was, "For example, can egg based seasonal or pandemic 14 influenza vaccine clinical data be submitted?" 15 The answer, "No, egg based seasonal or 16 17 pandemic influenza vaccine clinical data may not be submitted to satisfy the mandatory 18 criteria." 19 20 The third question, "Can seasonal mammalian cell-based influenza vaccine 21 clinical data be submitted?" And that just 22

goes back to the other question. "However,

clinical trial data for inter-pandemic or

seasonal mammalian cell-based influenza

vaccine candidates will satisfy this element

of the mandatory criteria."

So as we were reading the questions, we interpreted the question with the preamble to this that there was a concern that we were only looking for pandemic strains, and it's really whether we have seasonal or inter-pandemic candidate on your cell substrate. That clinical data will be acceptable, and will satisfy the mandatory criteria.

Question nine, "Will contractors

be reimbursed for their actual costs plus a

fixed fee subject to the limitation of costs,

or will their cost recovery be limited to

their estimated cost plus fixed fee, unless

actual costs are less than estimated costs?

Then it would be actual costs plus fixed fee,

as suggested in the language of the RFP,

regardless of whether actual costs exceed
estimates."

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And the answer from our

Contracting Office is, "The total Cost Plus 5 Fixed Fee that has been obligated at contract award cannot be exceeded without approval in 7 writing from the Contracting Officer. Actual costs, however, that are billed against the 8 9 current obligated amount will be reimbursed up 10 to the obligated amount, as long as they are reasonable, allocable, and allowable in 11 accordance with the FAR. Once the contractor 12 reaches 75 percent of the obligated amount, 13 the Contracting Officer must be notified in 14 writing in accordance with the Limitation of 15 Cost clause. At that time, BARDA will 16 determine whether or not additional funds will 17 be obligated to fund the anticipated cost 18 overrun under the contract. A determination 19 to fund the cost overrun as identified in the 20 21 revised estimate submitted by the Contractor does not affect the fixed fee, which remains 22

- 1 unchanged in a cost overrun situation.
- 2 Contractors who exceed the total Cost Plus
- 3 Fixed Fee on the contract without notification
- 4 in writing from the Contracting Officer do so
- 5 at their own risk."
- 6 That's a pretty standard setup for
- 7 our Cost Plus Fixed Fee contracts.
- 8 Question ten, "Would the
- 9 government consider amending the RFP in some
- 10 way to lessen the burden on potential
- 11 contractors? Alternatively, will HHS consider
- allowing the contractors to negotiate in good
- faith new terms, or to terminate the option
- 14 period if circumstances in the influenza
- 15 market deteriorate due to technology changes,
- or if other non-viable market conditions
- 17 prevail?"
- 18 You notice in the Q&A handout,
- there was a lengthy preamble to this one, with
- concerns around the market itself, and the
- length or duration of this contract. So, "As
- stated in the RFP, it is the commitment of the

offeror to maintain a facility in a manner 1 2. that will allow for the production of pandemic influenza vaccine throughout the duration of 3 this contract. The contractor has the 5 opportunity to propose contract modifications that support influenza vaccine technology 7 advancements. Please note that this contract 8 does not support the advanced development of 9 an influenza vaccine." 10 See if there's follow-up on that 11 one. Question eleven, "The facility 12 13 fully licensed for the manufacture of an influenza vaccine candidate must remain in a 14 state of readiness commensurate with the terms 15 of the contract." And, "The purpose of this 16

of the contract." And, "The purpose of this RFP is to support eligible contractors in the design, construction and licensure of a domestic facility to manufacture seasonal influenza vaccines. In order to remain in a state of readiness commensurate with the terms of the contract, the contractor must not

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1	compromise their ability to manufacture
2	licensed seasonal influenza vaccine in the
3	facility. However, if the facility is
4	utilized to manufacture other biologics, and
5	the contractor is able to maintain their
6	license to manufacture seasonal influenza,
7	then the U.S. government would not object."
8	So this was around the terms of a
9	multi-product facility, and we are not
10	supporting a multi-product facility in the
11	solicitation. However, if you can maintain
12	the licensure of your seasonal influenza
13	candidate in the facility, and still
14	manufacture other products, so be it.
15	Question 12, "May contractors
16	utilize equipment purchased under this RFP in
17	conjunction with non-contract related
18	activities at the facility so long as such
19	activities do not interfere with contract
20	performance?"
21	"Title and use rights in and to
22	any equipment purchased under this RFP will be

subject to provisions of Part II, Section I.5

of the RFP, and the provisions of the FAR Part

45, including, but not limited to FAR

45.301(f)." So you have to go back to your

RFP.

MR. CURRAN: The FAR does provide guidance on the use of government-furnished property, so the FAR will control what uses will be permitted. Of course, the language of the RFP and the FAR will determine on a threshold-basis whether or not equipment is government-furnished property for purposes of this contract.

MR. ANGELASTRO: The intention of the solicitation as it is now, remember from our draft proposal submission, and the questions that were received there, and the answers that were provided by BARDA on that draft is not the government's expectation to have any ownership of equipment or infrastructure under this solicitation per se, so it's more during the course of the base

1 period of the contract, what are the ownership 2 rights? And that's going to be spelled out in the language of the RFP and the FAR. 3 4 MR. WARF: Please note this does 5 not affect, or is not a comment upon previous contracts that are already in place. 7 MR. ANGELASTRO: Correct. was also clarified in previous questions, as 8 9 well. If there were other contracts that 10 you're under obligation on other contracts, 11 and the government does share ownership of the 12 equipment under those other contracts, that 13 remains in effect. Question thirteen, "Past 14 Performance Questionnaire is included as 15 Attachment 13. Please provide further 16 17 instruction as to the number of questionnaires to submit." 18 "The solicitation instructs the 19 20 offeror to submit information concerning their 21 last three contracts completed during the last

three years, or information for the last three

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1 contracts currently in process. It does not 2. require that the offeror submit the 3 questionnaire as part of their proposal, or forward the questionnaire to their past 5 performance references. Please insure that you furnish accurate, complete contact 7 information for references as specified in 8 your proposal to expedite the past performance 9 evaluation." 10 That is a key element of the 11 contract, and please follow those instructions. 12 13 Question fourteen, "Please clarify the definition of the term "Vaccine Candidate" 14 15 used throughout the RFP. Is the term in reference to a pre-pandemic vaccine, seasonal 16 17 vaccine, or both?" "Yes, the term "Vaccine Candidate" 18 19 refers to an offeror's seasonal and/or pre-20 pandemic influenza vaccine." So that we'll take a 10-15 minute 21 break, let you discussion some of the answers, 22

1 since you have the actual responses in front 2 of you, and then we'll reconvene for Q&A. 3 MS. MYRICK-HANCOCK: And as you exit, if you could just turn your cards face 4 5 down here at the end of the table, and we'll take a look at them and review your questions 7 during the break. **QUESTIONER 2:** Can we discuss -8 9 MS. MYRICK-HANCOCK: We'll 10 actually provide responses once we get back 11 from the break. 12 MR. CURRAN: But if you need to 13 discuss before the break, you have a question, that's fine. 14 15 QUESTIONER 2: Yes. 16 MS. MYRICK-HANCOCK: And please 17 don't indicate -- put your names on the cards. We like for this to remain anonymous. 18 19 (Whereupon, the proceedings went 20 off the record at 9:27:02 a.m., and went back 21 on the record at 9:47:19 a.m.) 22 MR. ANGELASTRO: All right. We're going to get started. We have a few questions
here.

First off, before I get started, I
want to thank everyone for attending today.

Want to thank everyone for attending today.

I know Dr. Perdue mentioned earlier, but
appreciate you coming down and going through
this proposal in detail, and actually asking
some really good questions. A couple of them
have been challenging for us to actually
respond to, and we hope that we're able to
clarify some of your questions or concerns
regarding this requirement.

So the first question that we're going to go through is, "Is it possible or likely that an amended RFP will be issued prior to the proposal submission deadline of September 29th?" Myself and Paquetta both feel that we will not be amending the RFP as it is in the system at this time, so no, we're going to keep it as it is.

I know there was a mention in the Q&A that there may be an amended RFP to

incorporate responses on indemnification and 1 That will be more or less discussed 2. 3 during actual contract negotiations at the 4 signing of the contract, so incorporate 5 whatever language is necessary around that. Paquetta, do you want to add 7 anything to that? MS. MYRICK-HANCOCK: No, that's 9 fine. 10 MR. ANGELASTRO: Okay. That was 11 the first question. The second question Charlie will take. 12 13 MR. CURRAN: "Can DHHS briefly comment a little further on FAR 45.301? 14 15 this allow use of equipment for other proprietary purposes when not used 16 17 specifically for production of U.S. government product?" 18 19 The provision - excuse me - let me 20 first comment on the provision of 45.301(f). 21 45.301(f) provides that in exchange for consideration as determined by the cognizant 22

Contracting Officer, and that would be at the time, the contractor may use government property for commercial use.

It goes on to say that up to 25

percent use for -- total use don't need to get

permission beyond the Contracting Officer. If

your use is going to exceed 25 percent, you

need permission from the head of the

contracting activity.

Now, the threshold question, of course, is going to be whether or not the equipment will be classifiable as government-furnished property. Remember, this is a cost-sharing contract, so some of the costs of purchasing this equipment will be -- use government funds, others will not. So to the extent that you may foresee use of some equipment for other purposes, and government funds are not used, then I would advise examining what the rules are, and they're set out in the RFP, I think, and they're also in the FAR. I don't -- from our perspective, I

don't think if it's not classified as
government-furnished property, then I don't
think that necessarily there will be an issue
from your end.

So there is a threshold issue of whether it's government-furnished property.

Then there's an issue of what will happen at the time, how much use. Do you intend to use it for commercial purposes? When the issue arises, that will be dealt with then as a contract administration issue.

MS. MYRICK-HANCOCK: All right.

The third question is, "It's highly likely that manufacturing costs will change substantially in the 20 plus years, as compared to the estimated costs that will be submitted in response to the RFP. The RFP indicates that the CPFF is limited to the costs submitted in our application. Will these costs be negotiable in the future? If not, costs included in proposal will likely

need to incorporate contingencies for future

1 unknowns."

I think the pre-submitted question
that we responded to indicated that there is
a notification that has to be made to the
Contracting Officer once you reach 75 percent
of funding. That notification includes a
revised estimate that's submitted by the
contractor.

It's not solely a determination on the part of the government whether or not we're going to fund. What we're looking for, once that revised estimate is submitted, is for you to support the increase in costs.

That is subject to negotiation.

Once those negotiations are completed, then we make a determination to fund. So that's the part that was actually missing from the response to the question, so you do get the opportunity to negotiate those costs when you provide that revised budget.

And that will result, once we can agree on what that amount is going to be, that will

actually result in a modification to the

contract. So there is a potential there to

get an increase in the total estimated costs

on the CPFF portion of the contract.

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We recognize that we are asking you to estimate costs far in the future, and we don't -- because this contract is a Cost Plus Fixed Fee, that's one of the reasons it is, is because we know that you can't predict those costs accurately in advance. So that provides you with the opportunity to come back and say hey, look, there have been changes in technical direction on the contract, or the current market has changed such that we're going to experience an increase in costs. Ιt gives you the opportunity to come in and request that modification, and to support your position.

The second part of this question says, "If not, costs included in the proposal will likely need to incorporate contingencies for future unknowns." Unfortunately, FAR does

not allow us to incorporate contingencies into 1 2. this contract. It's not an allowable cost, so 3 the process that I've just described is the 4 only way that we can provide some flexibility 5 in the CPFF on this contract. MR. ANGELASTRO: Okay. Thank you, 7 Paquetta. As far as -- if there are no 8 9 additional questions, or follow-up to that, we 10 can conclude the meeting. But if you feel 11 that there are -12 QUESTIONER 2: One more question. 13 MS. MYRICK-HANCOCK: We have a little bit of information here on the back. 14 15 The third part of this question is, "Will it be possible for BARDA to provide an electronic 16 17 copy of today's Q&A presented at today's conference?" 18 19 The hard copies that have been 20 provided to you as a handout are for your use 21 to take with you when you leave today. will be uploading the electronic information 22

from the results, the proceedings of this pre-1 2. solicitation pre-proposal conference no later 3 than September 19th. So you'll be able to go 4 out and review the information, and download 5 copies. And we actually are having a written 6 record of these proceedings done verbatim so 7 that you'll have the responses to the 8 additional follow-up questions, as well. 9 MR. ANGELASTRO: Okay. Thanks, 10 Paquetta. So if there are -- I'm going to go 11 around the room, and if there are additional 12 questions, nod your head, and we'll wait a few 13 minutes for you to write them down. Otherwise, we can conclude the pre-proposal conference. 14 15 All right. I'll, again, thank everyone for their attendance. Mike Perdue 16 17 has a few closing remarks. I do. 18 DR. PERDUE: I was just 19 thinking about how many agencies and sub-20 agencies have had some direct input into the 21 development of this RFP, and I stopped

counting at ten. As you might imagine, the

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1	CDC, NIH, FDA, DOD, DHS, a variety of people	
2	have had direct input in developing this,	
3	because it's a high difficulty, and I just	
4	wanted to thank Mike, and Tom, and Paquetta,	
5	in particular, for fielding all of this input,	
6	and putting together a package that I think	
7	ultimately now makes sense to everybody. I	
8	think there was great joy at the questions	
9	that we got, and the indications from the	
10	potential offerors that this was a good idea,	
11	and that it was going to work, and so this has	
12	been very productive for us.	
13	Again, thank you all for coming,	
14	and thank you guys for doing a good job.	
15	That's all I have.	
16	MR. ANGELASTRO: Okay. Thank you.	
17	Have a nice weekend.	
18	(Whereupon, the proceedings went	
19	off the record at 9:57:41 a.m.)	
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